HFA-305
Division of
Dockets Mgt.

Date of Approval Letter:

FREEDOM OF INFORMATION SUMMARY

SUPPLEMENTAL NEW ANIMAL DRUG APPLICATION

NADA 008-804

TM-50, TM-SOD, TM-100, and TM-100D Type A Medicated Articles
(oxytetracycline)

"to establish a zero-day pre-slaughter withdrawal period for cattle administered oxytetracycline at 10 mg/lb body weight per day for 14 days"

Sponsored by:
Phibro Animal Health

NADA 008-804

FOIS 1

1. GENERAL INFORMATION:

a. File Number:	NADA 008-804
b. Sponsor:	Phibro Animal Health 710 Route 46 East Suite 401 Fairfield, New Jersey 07004 Drug Labeler Code: 066104
c. Established Name:	Oxytetracycline quaternary salt equivalent to oxytetracycline hydrochloride
d. Proprietary Names:	TM-50, TM-SOD, TM-100, and TM-100D
e. Dosage Form:	Type A Medicated Article
f. How Supplied:	50 lb (22.6 kg) bags
g. How Dispensed:	OTC
h. Amount of Active Ingredients:	TM-50 and TM-SOD: 50 g/lb; TM-100 and TM-100D: 100 g/lb
i. Route of Administration:	Oral, via feed
j. Species/Class:	Chickens, turkeys, swine, cattle, sheep, lobsters, honey bees (on "D" product labeling only)
k. Recommended Dosage and Indications:	Chickens: Increased rate of weight gain and improved feed efficiency – 10-50 g/ton, feed continuously. Control of infectious synovitis caused by *Mycoplasma synoviae;* control of fowl cholera caused by *Pasteurella multocida* susceptible to oxytetracycline – 100-200 g/ton, feed continuously for 7-14 days. Control of chronic respiratory disease (CRD) and air sac infection caused by *Mycoplasma gallisepticum* and *Escherichia coli* susceptible to oxytetracycline – 400 g/ton, feed continuously for 7-14 days. Reduction of mortality due to air sacculitis (air sac infection) caused by *Escherichia coli* susceptible to oxytetracycline – 500 g/ton, feed continuously for 5 days.

Turkeys: For growing turkeys for increased rate of weight gain and improved feed efficiency – 10-50 g/ton, feed continuously. Control of hexamitiasis caused by *Hexamita meleagridis* susceptible to oxytetracycline – 100 g/ton, feed continuously for 7-14 days. Control of infectious synovitis caused by *Mycoplasma synoviae* susceptible to oxytetracycline – 200 g/ton, feed continuously for 7-14 days. Control of complicating bacterial organisms associated with bluecomb (transmissible enteritis, coronaviral enteritis) susceptible to oxytetracycline – 25 mg/lb of body weight daily, feed continuously for 7-14 days.

Swine: Increased rate of weight gain and improved feed efficiency – 10-50 g/ton, feed continuously. Treatment of bacterial enteritis caused by *Escherichia coli* and *Salmonella choleraesuis* susceptible to oxytetracycline and treatment of bacterial pneumonia caused by *Pasteurella multocida* susceptible to oxytetracycline – 10 mg/lb of body weight daily, feed continuously for 7-14 days. For breeding swine for control and treatment of Leptospirosis (reducing the incidence of abortion and shedding of leptospirae) caused by *Leptospira pomona* susceptible to oxytetracycline – 10 mg/lb of body weight daily, feed continuously for not more than 14 days.

Calves including Preruminating (Veal) Calves, Beef Cattle, and Non-Lactating Dairy Cattle: For calves (up to 250 lb) for increased rate of weight gain and improved feed efficiency – 0.05-0.1 mg/lb of body weight daily, feed continuously. For calves (250-400 lb) for increased rate of weight gain and improved feed efficiency – 25 mg/head/day, feed continuously. For growing cattle (over 400 lb) for increased rate of weight gain, improved feed efficiency, and reduction of liver condemnation due to liver abscesses – 75 mg/head/day, feed continuously. For prevention and treatment of the early stages of shipping fever complex – 0.5 to 2.0 g/head/day, feed 3 to 5 days before and after

arrival in feedlots. Treatment of bacterial enteritis caused by *Escherichia coli* and bacterial pneumonia (shipping fever complex) caused by *Pasteurella multocida* susceptible to oxytetracycline – 10 mg/lb of body weight daily, feed continuously for 7-14 days.

Sheep: Increased rate of weight gain and improved feed efficiency – 10-20 g/ton, feed continuously. Treatment of bacterial enteritis caused by *Escherichia coli* and bacterial pneumonia caused by *Pasteurella multocida* susceptible to oxytetracycline - 10 mg/lb of body weight daily, feed continuously for 7-14 days.

Honey bees: (TM-SOD and TM-100D only): Control of American foulbrood caused by *Bacillus larvae* and European foulbrood caused by *Streptococcus pluton* susceptible to oxytetracycline – 200 mg/colony.

Lobsters: Control of gaffkemia in lobsters caused by *Aerococcus viridans* – 1 g/lb of medicated feed, feed for 5 days as the sole ration.

l. Pharmacological Category: Antimicrobial

m. Effect of Supplement: This supplement establishes a zero-day pre-slaughter withdrawal period for cattle administered oxytetracycline at 10 mg/lb/day for 14 days.

2. EFFECTIVENESS:

No further effectiveness data were required for the approval of this supplemental application.

3. ANIMAL SAFETY:

No further target animal safety data were required for the approval of this supplemental application.

4. HUMAN SAFETY:

a. Toxicity:

No further basic toxicology studies were required for the approval of this supplemental application. However, CVM currently requires the sponsors to submit an assessment concerning the effects of antimicrobial residues present in the edible tissues of food animals on the intestinal flora of the consumer. The assessment submitted by the sponsor to comply with the human food safety requirements for antimicrobial drugs showed that the consumption of oxytetracycline residues present in edible tissues of cattle treated with 10 mg/lb/day for 14 days would not adversely affect the human intestinal flora, even when the complete meal basket is consumed in one day.

b. Safe Concentrations of Total Residues:

As documented in the FOI Summary dated March 28, 1996, for NADA 113-232. The safe concentration for total tetracycline microbiological activity was limited to 1 ppm in the total diet (1.5 mg/person/day) (61 FR 67453), equal to an ADI of 25 micrograms per kilogram of body weight per day.

C Tolerance for the Marker Residue:

Tolerances for oxytetracycline have been codified previously under 21 CFR 556.500 (61 FR 67453, December 23, 1996; 66 FR 46370, September 5,2001). Tolerances are established for the sum of residues of the tetracyclines in tissues of beef cattle, dairy cattle, calves, swine, sheep, chickens, turkeys, catfish, lobsters, and salmonids as follows: 2 parts per million (ppm) in muscle, 6 ppm in liver, 12 ppm in fat and kidney, and 0.3 ppm in milk.

d. Study Establishing the Withdrawal Period in Cattle:

Phibro Study Number USD 123-016

1. Purpose: A tissue residue study was conducted to quantify the concentration of oxytetracycline activity in edible tissues of cattle after oral administration, in feed, of oxytetracycline at a dose of 11 mg of oxytetracycline hydrochloride activity/lb of body weight (BW) for 14 days.

2. Investigators: Colorado Animal Research Enterprises (CARE), 6200 E. County Rd. 56, Fort Collins, CO 80524

3. Animals: six crossbred beef steers and six heifers

4. Dosage form and dosage: medicated feed at a dose of 11 mg oxytetracycline hydrochloride/lb BW/day for 14 consecutive days.

5. Parameters measured and assay: Oxytetracycline (parent) residues were measured in liver, kidney, muscle, and fat using the regulatory analytical (microbiological) method. LOQ for liver and kidney was 100 ppb; for muscle and fat the LOQ was 75 ppb (microassay).

6. Results: Oxytetracycline concentrations in the edible tissues of treated cattle are summarized in Table 6.1.

Table 6.1: Concentration of oxytetracycline (ppm) in the tissues of cattle treated with oxytetracycline medicated feed at a dose of 11 mg/lb/day and slaughtered at practical zero withdrawal.

Gender	Tissue			
	Kidney	**Liver**	**Muscle**	**Fat**
Heifers	1.818±0.439	0.671±0.175	0.181±0.057	ND*
Steers	1.312±0.704	0.796±0.211	0.197h0.091	ND
Overall	1.247±0.563	0.734±0.196	0.189±0.073	ND

*Residues were not detected in fat.

These data were used to calculate the single point 99th percentile upper tolerance limit (with 95% confidence) for oxytetracycline residues at zero withdrawal for kidney, liver, and muscle. The upper tolerance limit values are summarized in Table 6.2.

Table 6.2: Calculated tissue-specific upper tolerance limits (ppm) for oxytetracycline residues in cattle treated with medicated feed at a dose of 11 mg/lb/day and slaughtered at practical zero withdrawal.

Gender	Tissue		
	Kidney	**Liver**	**Muscle**
Heifers	3.40	1.56	0.47
Steers	4.88	1.87	0.66
Overall	3.36	1.47	0.46

The calculated upper tolerance limit value for each tissue is significantly less than the tissue-specific tolerance codified under 21 CFR 556.500. Therefore, it is concluded that the use of the oxytetracycline Type A Medicated Articles in cattle to provide oxytetracycline at doses up to 10 mg/lb body weight/day qualifies for a zero withdrawal.

e. Regulatory Method for Residues:

The regulatory analytical method for detection of residues of the drug is a microbiological test using *Bacillus cereus* var. *mycoides* (ATCC 11778). The method

is as published by the Food and Drug Administration, "Antibiotic Residues in Milk, Dairy Products, and Animal Tissues: Method, Reports, and Protocols," revised October 1968, reprinted December 1974.

f. Microbial Food Safety Assessment:

This NADA supplement establishes a zero-day pre-slaughter withdrawal period for cattle treated with 10 mg oxytetracycline/lb body weight per day for 14 days. Because this change to NADA 008-804 does not change the product indication, dose, duration, or other conditions of use beyond the change in withdrawal period, an evaluation of Microbial Food Safety was determined not to be necessary at this time for this supplemental approval to this approved product.

5. AGENCY CONCLUSIONS:

The data submitted in support of this supplemental NADA satisfy the requirements of Section 512 of the Federal Food, Drug, and Cosmetic Act and 21 CFR Part 514 of the implementing regulations. The data demonstrate that TM-50, TM-100, TM-SOD, and TM-100D Type A Medicated Articles are safe at a zero-day pre-slaughter withdrawal period when these products are administered to cattle for 14 days at a level of 10 mg/lb body weight/day in feed.

The Center for Veterinary Medicine has concluded that, for this product, adequate directions of use by the layperson have been provided and the product will have over-the-counter (OTC) status. Label directions provide detailed instructions in plain language. The drug product is not a controlled substance. Thus, the NADA retains OTC status, and the labeling is adequate for the intended use.

This approval does not qualify for marketing exclusivity under section 512(c)(2)(F)(iii) of the Federal Food, Drug, and Cosmetic Act.

Under the Center's supplemental policy (21 CFR 514.106(b)(2)), this is a Category II change. The approval of this change required a reevaluation of certain safety data in the parent application.

6. ATTACHMENTS:

Facsimile labeling is attached as indicated below:

A. TM-50, TM-100, TM-SOD, and TM-100D Type A Medicated Articles

B. Oxytetracycline Type B and C Blue Bird labels

TM-50®

TYPE A
MEDICATED ARTICLE

MIXING AND USE DIRECTIONS

Thoroughly mix the amount of this premix according to the directions below with at least an equal amount by weight of feed formula ingredients prior to blending into a complete feed.

TAKE TIME OBSERVE LABEL DIRECTIONS

Indications for Use	Oxytetracycline Amount	lb of TM-50/ton
CHICKENS		
Increased rate of weight gain and improved feed efficiency	10-50 g/ton Feed continuously	0.2-1.0
Control of infectious synovitis caused by *Mycoplasma synoviae*; control of fowl cholera caused by *Pasteurella multocida* susceptible to oxytetracycline	100-200 g/ton Feed continuously for 7-14 days	2-4
Control of chronic respiratory disease (CRD) and air sac infection caused by *Mycoplasma gallisepticum* and *Escherichia coli* susceptible to oxytetracycline	400 g/ton Feed continuously for 7-14 days	8
Reduction of mortality due to air sacculitis (air sac infection) caused by *Escherichia coli* susceptible to oxytetracycline	500 g/ton Feed continuously for 5 days	10
WARNING: At 500 g/ton level, withdraw 24 hours before slaughter. Zero-day withdrawal period for lower use levels. In low calcium feeds withdraw 3 days before slaughter. Do not administer to chickens producing eggs for human consumption.		
TURKEYS		
For growing turkeys for increased rate of weight gain and improved feed efficiency	10-50 g/ton Feed continuously	0.2-1.0
Control of hexamitiasis caused by *Hexamita meleagridis* susceptible to oxytetracycline	100 g/ton Feed continuously for 7-14 days	2
Control of infectious synovitis caused by *Mycoplasma synoviae* susceptible to oxytetracycline	200 g/ton Feed continuously for 7-14 days	4
Control of complicating bacterial organisms associated with bluecomb (transmissible enteritis, coronaviral enteritis) susceptible to oxytetracycline	25 mg/lb of body weight daily Feed continuously for 7-14 days	10.7[a]
WARNING: At 200 g/ton use level or higher, withdraw 5 days before slaughter. Zero-day withdrawal period for lower use levels. Do not administer to turkeys producing eggs for human consumption.		
SWINE		
Increased rate of weight gain and improved feed efficiency	10-50 g/ton Feed continuously	0.2-1.0
Treatment of bacterial enteritis caused by *Escherichia coli* and *Salmonella choleraesuis* susceptible to oxytetracycline and treatment of bacterial pneumonia caused by *Pasteurella multocida* susceptible to oxytetracycline	10 mg/lb of body weight daily Feed continuously for 7-14 days	10[b]
For breeding swine for control and treatment of Leptospirosis (reducing the incidence of abortion and shedding of leptospirae) caused by *Leptospira pomona* susceptible to oxytetracycline	10 mg/lb of body weight daily Feed continuously for not more than 14 days	10[b]
CALVES INCLUDING PRE-RUMINATING (VEAL) CALVES, BEEF CATTLE, AND NONLACTATING DAIRY CATTLE		
For calves (up to 250 lb) for increased rate of weight gain and improved feed efficiency	0.05-0.1 mg/lb of body weight daily Feed continuously	0.1-0.2[c]
For calves (250-400 lb) for increased rate of weight gain and improved feed efficiency	25 mg/head/day Feed continuously	0.5[d]
For growing cattle (over 400 lb) for increased rate of weight gain, improved feed efficiency, and reduction of liver condemnation due to liver abscesses	75 mg/head/day Feed continuously	1.5[d]
Prevention and treatment of the early stages of shipping fever complex (Feed 3-5 days before and after arrival in feedlots)	0.5-2.0 g/head/day	10-40[d]
Treatment of bacterial enteritis caused by *Escherichia coli* and bacterial pneumonia (shipping fever complex) caused by *Pasteurella multocida* susceptible to oxytetracycline	10 mg/lb of body weight daily Feed continuously for 7-14 days	100[e]
WARNING: When used in milk replacers, the treatment claim (10 mg/lb) is limited to bacterial enteritis caused by *Escherichia coli* only.		
SHEEP		
Increased rate of weight gain and improved feed efficiency	10-20 g/ton Feed continuously	0.2-0.4
Treatment of bacterial enteritis caused by *Escherichia coli* and bacterial pneumonia caused by *Pasteurella multocida* susceptible to oxytetracycline	10 mg/lb of body weight daily Feed continuously for 7-14 days	24[f]
WARNING: 5-day withdrawal before slaughter at 10 mg/lb dosage.		
LOBSTERS		
Control of gaffkemia in lobsters caused by *Aerococcus viridans*	1 g/lb of medicated feed Feed for 5 days as the sole ration	40
WARNING: Withdraw from feed 30 days before harvesting lobsters.		

[a] If bird weighs 10 lb, consuming 0.5 lb of complete feed per day
[b] If pig weighs 100 lb, consuming 4 lb of complete feed per day
[c] If calf weighs 100 lb, consuming 2 lb of complete starter feed per day
[d] Include in feed supplement based on consumption of 2 lb of supplement per head per day
[e] If animal weighs 500 lb, consuming 2 lb of supplement per head per day
[f] If lamb weighs 50 lb, consuming 1 lb of supplement per head per day

101-9001-02 FOR USE IN DRY FEEDS ONLY. NOT FOR USE IN LIQUID FEED SUPPLEMENTS.

TM-50®
Type A Medicated Article

Phibro ANIMAL HEALTH

TM-5 ®

TYPE A
MEDICATED AR ICLE

Active Drug Ingredient:
Oxytetracycline (from oxytetracycline quaternary salt)
equivalent to oxytetracycline hydrochloride .... 50 g/l

CAUTION: For use in manufacturing medicated animal feeds only.

CAUTION: Certain components of animal feeds, including medicated premixes, possess properties that may be a potential health hazard or a source of personal discomfort to certain individuals who are exposed to them. Human exposure should, therefore, be minimized by observing the general industry standards for occupational health and safety.

Precautions such as the following should be considered: dust masks or respirators and protective clothing should be worn; dust-arresting equipment and adequate ventilation should be utilized; personal hygiene should be observed; wash before eating or leaving a work site; be alert for signs of allergic reactions—seek prompt medical treatment if such reactions are suspected.

STORE IN A DRY, COOL PLACE

SEE BACK PANEL FOR COMPLETE MIXING AND USE DIRECTIONS

TM-50 is a Phibro Animal Health registered trademark for Oxytetracycline HCl
Phibro Animal Health, Inc., Fairfield, NJ 07004

Net Weight 50 lb (22.6 kg)

NADA #8-804, Approved by FDA

101-9001-02

Distributed by

Phibro ANIMAL HEALTH

Phibro ANIMAL HEALTH
TM-50®
Type A Medicated Article

TM-50®

TYPE A
MEDICATED ARTICLE

Active **Drug** Ingredient:
Oxytetracycline (from oxytetracycline quaternary salt)
equivalent to oxytetracycline hydrochloride . . . . . **50 g/lb**

CAUTION: For use in manufacturing medicated animal feeds only.

CAUTION: Certain components of animal feeds, including medicated premixes, possess properties that may be a potential health hazard or a source of personal discomfort to certain individuals who are exposed to them. Human exposure should, therefore, be minimized by observing the general industry standards for occupational health and safety.

Precautions such as the following should be considered: dust masks or respirators and protective clothing should be worn; dust-arresting equipment and adequate ventilation should be utilized; personal hygiene should be observed; wash before eating or leaving a work site; be alert for signs of allergic reactions—seek prompt medical treatment if such reactions are suspected.

STORE IN A DRY, COOL PLACE

SEE BACK PANEL FOR COMPLETE MIXING AND USE DIRECTIONS

TM-50 *is* a Phibro Animal Health registered trademark for Oxytetracycline HCl
Phibro Animal Health, Inc., Fairfield, NJ 07004

Net Weight 50 lb (22.6 kg)

NADA #8-804, Approved by FDA

101-9001-02

Distributed by

Phibro
ANIMAL HEALTH

TM-50®

TYPE A
MEDICATED ARTICLE

MIXING USE DIRECTIONS · KE TIME · OBSERVE LABEL DIRECTIONS

Thorough ... the amou... o this premix ...ct rdi...g to the directions be...w w that ...ast
an equal ...nt by weigh... ...t feed formula ...ng ...uid...nts prior to blending ...to a complete feed.

Indicati...	...or Use	Oxytetracycline Amount	lb of TM-50/ton
CHICKEN			
Increased ...	...of weight g...in ...nd Improvec...eed...et ...iciency	**10-50** g/ton Feed continuously	0.2-1.0
Control of ... fowl chole...	...llous synov...Ia...aused by M...*oplasma synoviae*; Control o... Jsed by Pa...*ella multocid*...susceptible to oxytetracycli...e	100-200 **g/ton** Filed continuously lor 7-14 days	2-4
Control of ... *Mycoplasm...*	...ic respirat...y ...isease (CRD) ...nd air sac Infection caused ...y ...*Illisepticum* ...nd *Escherichia ...oli* ...ius ...eptible to **oxytetracyc...ne**	400 g/ton **Feed** continuously for 7-14 days	8
Reduction ... *Escherichi...*	...rtality due ...a...saccullitis (...r sac ...fection) caused by ... susceptibl... to oxytetracycli...	500 g/ton Feed continuously for 5 days	10
◆**WARNI...** ...calciu...m	...t 500 g/to... ...ed in...withdraw... ...ds withdra... ...3 days before	24 hours before slaughter. ...ero-day withdrawal period for lower use levels. In low ...o chickens producing eggs lor human consumption.	
TURKEYS			
for growin...	...eys for inc...as...d rate of we...ht gai...n and improved feed e...iciency	**10-50 g/ton** Feed continuously	0.2-1.0
Conlrol of ... to oxytetrac...	...itiasis caus...d by *Hexamita ...eleagridis* susceptible	100 g/ton Feed continuously for 7-14 days	2
Control of ... susceptible	...ous synovit...caused by *Myc...plasma synoviae*	200 g/ton **Feed** continuously for 7-14 days	4
Control of c... (transmissil...	...cating bacl...ial organisms a...sociati...d with bluecomb ...eritis, corc...a...al enteritis) ...usceptible to oxytetracycline	**25** mg/lb of body weight daily **Feed continuously** lor 7-14 days	16.7'
	◆**ARNING: A... 20...g/ton use l...vel or higher, withdraw 5 days before slaughter. Zero-day withdrawal ...riod for lo...er use levels. ...not administer to turkeys producing eggs for human consumption.◆**		
SWINE			
Treatment of b...terial enteritis caused by *Esche...chia coli* and bacteria pneumonia (sh...ping fever com...lex) caused by *...steurella multocida* susceptible to ...tracycline			
Treatment of b...terial enteritis caused by Escher...chia coli* and bacterial pneumonia caus...d by *Pasteurel...multocida* susc...ptible to oxytetracyclin...		**Feed** continuously lor 7-14 days	
	◆**WARNING: 5-da...** withdrawal before slaughter at 10 mg/lb dosage.◆		
LOBSTERS			
Control of gaffke... ...in lobsters... ...aused by *Aeroco...cus viridans*		1 **g/lb** of medicated feed feed lor 5 drys **as the** sole ration	40
	◆**WARNING:** Withd...w from feed *30* drys before harvesting lobsters,◆		

'If bird weighs 10...lb ...consuming ...6 ...ll of complete feed por day
'If pig weighs 10... ...lb ...consuming 1 lb of complete ...ed per day
'If calf weighs 10... ...lb, consuming 2 lb of **complete** ...tarter feed per day
'Include in feed a... ...pplement base... on consumption of 2 lb of ...upplement per herd per day
'If animal weighs ...00 lb, consuming 2 lb of supplem...ent per herd per day
'If lamb weighs 6... lb consuming 1 lb of supplemen... per head per day

TM-50® D

Type A Medicated Article

Phibro ANIMAL HEALTH

OPEN
PULL NARROW TAPE

TM-50® D

TYPE A MEDICATED ARTICLE

Active Drug Ingredient:
Oxytetracycline (from oxytetracycline quaternary salt) equivalent to oxytetracycline hydrochloride ..... 50 g/lb

CAUTION: For use in manufacturing medicated animal feeds only.

CAUTION: Certain components of animal feeds, including medicated premixes, possess properties that may be a potential health hazard or a source of personal discomfort to certain individuals who are exposed to them. Human exposure should, therefore, be minimized by observing the general industry standards for occupational health and safety.

Precautions such as the following should be considered: dust masks or respirators and protective clothing should be worn; dust-arresting equipment and adequate ventilation should be utilized; personal hygiene should be observed; wash before eating or leaving a work site; be alert for signs of allergic reactions—seek prompt medical treatment if such reactions are suspected.

STORE IN A DRY, COOL PLACE

SEE BACK PANEL FOR COMPLETE MIXING AND USE DIRECTIONS AND WARNINGS

TM-50 is a Phibro Animal Health registered trademark for Oxytetracycline HCl
Phibro Animal Health, Inc., Fairfield, NJ 07004

Net Weight 50 lb (22.6 kg)

NADA #8-804, Approved by FDA
7810000
101-0003-02

Phibro ANIMAL HEALTH

Phibro ANIMAL HEALTH

50 D

Type A Medicated Article

TM-50®

(01) 1 03 66104 79190 7

TM-50® D

TAKE THE ORIGINAL LABEL DIRECTIONS

101-0003-02

Phibro ANIMAL HEALTH
Fairfield, NJ 07004

TM-50® D

TYPE A
MEDICATED ARTICLE

Active Drug Ingredient:
Oxytetracycline (from oxytetracycline quaternary salt) equivalent to oxytetracycline hydrochloride ..... **50 g/lb**

CAUTION: For use in manufacturing medicated animal feeds only.

CAUTION: Certain components of animal feeds, including medicated premixes, possess properties that may be a potential health hazard or a source of personal discomfort to certain individuals who are exposed to them. Human exposure should, therefore, be minimized by observing the general industry standards for occupational health and safety.

Precautions such as the following should be considered: dust masks or respirators and protective. clothing should be worn; dust-arresting equipment and adequate ventilation should be utilized; personal hygiene should be observed; wash before eating or leaving a work site; be alert for signs of allergic reactions—seek prompt medical treatment if such reactions are suspected.

STORE IN A DRY, COOL PLACE

SEE BACK PANEL FOR COMPLETE MIXING AND USE DIRECTIONS AND WARNINGS

TM-50 is a Phibro Animal Health registered trademark for Oxytetracycline HCl
Phibro Animal Health, Inc., Fairfield, NJ 07004

Net Weight 50 lb (22.6 kg)

NADA #8-804, Approved by FDA
7919000
101-9003-02

Phibro
ANIMAL HEALTU

TM-50®D

TAKE TIME  SERVE LABEL DIRECTIONS

Mixing and Use Directions

Thoroughly mix the amount of this premix according to the directions below with at least an equal amount by weight of feed formula ingredients prior to blending into a complete feed.

Indications for Use	Oxytetracycline Amount	lb of TM-50D/ton
CHICKENS		
Increased rate of weight gain and improved feed efficiency	10-50 g/ton Feed continuously	0.2-1.0
Control of infectious synovitis caused by *Mycoplasma synoviae*; control of fowl cholera caused by *Pasteurella multocida* susceptible to oxytetracycline	100-200 g/ton Feed continuously for 7-14 days	2-4
Control of chronic respiratory disease (CRD) and air sac infection caused by *Mycoplasma gallisepticum* and *Escherichia coli* susceptible to oxytetracycline	400 g/ton Feed continuously for 7-14 days	8
Reduction of mortality due to air sacculitis (air sac infection) caused by *Escherichia coli* susceptible to oxytetracycline	500 g/ton Feed continuously for 5 days	10
WARNING: At 500 g/ton feed, withdraw 24 hours before slaughter. Zero-day withdrawal period for lower use levels. In low calcium feeds withdraw 3 days before slaughter. Do not administer to chickens producing eggs for human consumption.		
TURKEY:		
For growing turkeys for increased rate of weight gain and improved feed efficiency	10-50 g/ton Feed continuously	02.10
Control of heramitiasis caused by *Hexamita meleagridis* susceptible to oxytetracycline	100 g/ton Feed continuously for 7-14 days	2
Control of infectious synovitis caused by *Mycoplasma synoviae* susceptible to oxytetracycline	200 g/ton Feed continuously for 7-14 days	1
Control of complicating bacterial organisms associated with bluecomb (transmissible enteritis coronaviral enteritis) susceptible to oxytetracycline	25 mg/lb of body weight dilly Feed continuously for 7-11 days	16.7[1]
WARNING: At 200 g/ton use level or higher, withdraw 5 days before slaughter. Zero-day withdrawal period for lower use levels. Do not administer to turkeys producing eggs for human consumption.		
SWINE		
Increased rate of weight gain and improved feed efficiency	10-50 g/ton Feed continuously	0.2-1.0
Treatment of bacterial enteritis caused by *Escherichia coli* and *Salmonella choleraesuis* susceptible to oxytetracycline and treatment of bacterial pneumonia caused by *Pasteurella multocida* susceptible to oxytetracycline	10 mg/lb of body weight daily Feed continuously for 7-14 days	10[2]
For breeding swine for control and treatment of Leptospirosis (reducing the incidence of abortion and shedding of leptospirae) caused by *Leptospira pomona* susceptible to oxytetracycline	10 mg/lb of body weight daily Feed continuously for not more than 14 days	10[2]
CALVES including pre-ruminating (veal) calves, **BEEF CATTLE, AND NONLACTATING DAIRY CATTLE**		
For calves (up to 250 lb) for increased rate of weight gain and improved feed efficiency	0.05-0.1 mg/lb of body weight dilly Feed continuously	0.1-0.2[3]
For calves (250-400 lb) for increased rate of weight gain and improved feed efficiency	25 mg/head/day Feed continuously	0.5[4]
For growing cattle (over 400 lb) for increased rate of weight gain, improved feed efficiency, and reduction of liver condemnation due to liver abscesses	75 mg/head/day Feed continuously	15[4]
Prevention and treatment of the early stages of shipping fever complex (Feed 3-5 days before and after arrival in feedlots)	0.5-2.0 g/head/day	10-40[5]
Treatment of bacterial enteritis caused by *Escherichia coli* and bacterial pneumonia (shipping fever complex) caused by *Pasteurella multocida* susceptible to oxytetracycline	10 mg/lb of body weight daily Feed continuously for 1-14 days	100[3]
WARNING: When used in milk replacers, the treatment claim (10 mg/lb) is limited to bacterial enteritis caused by *Escherichia coli* only.		
SHEEP		
Increased rate of weight gain and improved feed efficiency	10-20 g/ton Feed continuously	0.2-0.4
Treatment of bacterial enteritis caused by *Escherichia coli* and bacterial pneumonia caused by *Pasturella multocida* susceptible to oxytetracycline	10 mg/lb of body wsight daily Feed continuously for 7-14 days	24[6]
WARWIHG: 5-day withdrawal before rirughirr at 10 mg/lb dosage.		
HONEY BEES		
Control of American Foulbrood caused by *Bacillus larvae*, and European Foulbrood caused by *Streptococcus pluton* susceptible to oxytetracycline	200 mg/colony	See Mixing Directions below
WARHINC: Remove at least 6 weeks prior to main honey flow.		
LOBSTERS		
Control of gaffkemia in lobsters caused by *Aerococcus viridans*	1 g/lb of medicated feed Feed for 5 days as the sole ration	40
WARNING: Withdraw from feed 30 days before harvesting lobsters.		

[1] If bird weighs 10 lb, consuming 0.5 lb of complete lead per day
[2] If pig weighs 100 lb, consuming 4 lb of complete feed per day
[3] If calf weighs 100 lb, consuming 2 lb of complete starter feed per day
[4] Include in feed supplement based on consumption of 2 lb of supplement per head par day
[5] If animal weighs 500 lb, consuming 2 lb of supplement par head per day
[6] If lamb weighs 60 lb, consuming 1 lb of supplement per head per day

FOR USE IN DRY FEEDS ONLY. NOT FOR USE IN LIQUID FEED SUPPLEMENTS.

Mixing and Use Directions for Honey Iass

Due to the high drug concentration of this product, an intermediate mixture must be prepared for use with bees. To prepare this intermediate mixture add 7 lb of TM-500 to 100 lb of powdered sugar and mix well. This mixture contains approximately 200 mg of oxytetracycline hydrochloride activity per oz.

Dusting Directions: Apply 1 oz (200 mg oxytetracycline) of this mixture per colony. Apply the dust on the outer parts or ends of the frames.

Syrup Directions: Use 1 oz (200 mg oxytetracycline) of this mixture per 6 lb jar containing 1:1 sugar syrup (equal parts sugar and water w/w) per colony. Dissolve in a small quantity of water before adding to syrup. Bulk feed the syrup using leader pails or division board feeders or by filling the combs.

Administer in 3 applications of sugar syrup or 3 dustings at 4- to 5-day intervals. The drug should be laid in the spring or fall and consumed by the bora before main honey flow begins to avoid contamination el production honey.

Extender Patty Directions: Use 4 oz (800 mg oxytetracycline) of this mixture mixed with 165 g of vegetable shortening (Crisco® or equivalent) and 330 g or sugar. The patties are placed on the top bars of the brood nest frames.

WARNING: This mixture should be fad in the spring or fall and consumed by the bees before main honey flow begins to avoid contamination of production honey. Honey stored during medication periods in combs for surplus honey should be removed following final medication of the bre colony and must not be used for humin food. Honey from bee colonies likely to be infected with foulbrood should not be used for preparations of medicated syrup supplements since it may be contaminated with spores of foulbrood and may result in spreading the disease. Remove at least 6 weeks before main honey flow. Do not use in a manner contrary to state apiary laws and regulations. Each state has specific regulations relative to disease control and medications. Contact lhr appropriate official or state departments of agriculture for specific inter- and intrastate lawr and regulations.

Crisco® is a trademark of Procter & Gamble, Cincinnati, OH 45202

101-9003-02

TM-100®

TYPE A
MEDICATED ARTICLE

TM-100®

TYPE A
MEDICATED ARTICLE

Active Drug Ingredient:
Oxytetracycline (from oxytetracycline quaternary salt)
equivalent to oxytetracycline hydrochloride ..... 100 g/lb

CAUTION: For use in manufacturing medicated animal feeds only.

CAUTION: Certain components of animal feeds, including medicated premixes, possess properties that may be a potential health hazard or a source of personal discomfort to certain individuals who are exposed to them. Human exposure should, therefore, be minimized by observing the general industry standards for occupational health and safety.

Precautions such as the following should be considered: dust masks or respirators and protective clothing should be worn; dust-arresting equipment and adequate ventilation should be utilized; personal hygiene should be observed; wash before eating or leaving a work site; be alert for signs of allergic reactions—seek prompt medical treatment if such reactions are suspected.

STORE IN A DRY, COOL PLACE

SEE BACK PANEL FOR COMPLETE MIXING AND USE DIRECTIONS

TM-100 is a Phibro Animal Health registered trademark for Oxytetracycline HCl
Phibro Animal Health, Inc., Fairfield, NJ 07004

Net Weight 50 lb (22.6 kg)

NADA #8-804, Approved by FDA

181-00052-02

Distributed by

Phibro
ANIMAL HEALTH

TM-100®

Type A Medicated Article

Phibro
ANIMAL HEALTH

TM-100®

Type A Medicated Article

TM-100®

TYPE A
MEDICATED ARTICLE

Active Drug Ingredient:
Oxytetracycline (from oxytetracycline quaternary salt)
equivalent to oxytetracycline hydrochloride ..... **100 g/lb**

CAUTION: For use in manufacturing medicated animal feeds only.

CAUTION: Certain components of animal feeds, including medicated premixes, possess properties that may be a potential health hazard or a source of personal discomfort to certain individuals who are exposed to them. Human exposure should, therefore, be minimized by observing the general industry standards for occupational health and safety.

Precautions such as the following should be considered: dust masks or respirators and protective clothing should be worn; dust-arresting equipment and adequate ventilation should be utilized; personal hygiene should be observed; wash before eating or leaving a work site; be alert for signs of allergic reactions—seek prompt medical treatment if such reactions are suspected.

STORE IN A DRY, COOL PLACE

SEE BACK PANEL FOR COMPLETE MIXING AND USE DIRECTIONS

Phibro Animal Health, Inc., Fairfield, NJ 07004

Net Weight 50 lb (22.6 kg)

NADA #8-804, Approved by FDA

101-9002-02

Distributed by

TM-100®

TYPE A MEDICATED ARTICLE

MIXING AND USE DIRECTIONS TAKE TIME OBSERVE LABEL DIRECTIONS

Thoroughly mix the amount of this premix according to the directions below with at least an equal amount by weight of feed ingredients to obtain a uniform mixture.

Indications for Use	Oxytetracycline Amount	lb of TM-100/ton
CHICKENS		
Increased rate of weight gain and improved feed efficiency	10-50 g/ton Feed continuously	0.1-0.5
Control of infectious synovitis caused by *Mycoplasma synoviae* susceptible to oxytetracycline	100-200 g/ton Feed continuously for 7-14 days	1-2
Control of chronic respiratory disease (CRD) and air sac infection caused by *Mycoplasma gallisepticum* and *Escherichia coli* susceptible to oxytetracycline	400 gm/ton Feed continuously for 7-14 days	4
Reduction of mortality due to air sacculitis (air sac infection) caused by *Escherichia coli* susceptible to oxytetracycline	500 gm/ton Feed continuously for 5 days	5
▶ WARNING: At 50 gm/ton use level or higher, withdraw 24 hours prior to slaughter. Zero-day withdrawal period for lower use levels. In low calcium feeds withdraw 3 days prior to slaughter. Do not administer to chickens producing eggs for human consumption. ◀		
TURKEY		
For growing turkeys for increased rate of weight gain and improved feed efficiency	10-50 g/ton Feed continuously	0.1-0.5
Control of infectious synovitis caused by *Hexamita meleagridis* susceptible to oxytetracycline	100 gm/ton Feed continuously for 7-14 days	1
Control of infectious synovitis caused by Mycoplasma *synoviae* susceptible to oxytetracycline	200 g/ton Feed continuously for 7-14 days	2
Control of complicating bacterial organisms associated with bluecomb (transmissible enteritis, coronaviral enteritis) susceptible to oxytetracycline	25 mg/lb of body weight daily Feed continuously for 7-14 days	0.13
▶ WARNING: At 200 g/ton use level or higher, withdraw 5 days prior to slaughter. Zero-day withdrawal period for lower use levels. Do not administer to turkeys producing eggs for human consumption. ◀		
SWINE		
Increased rate of weight gain and Improved feed efficiency	10-50 g/ton Feed continuously	0.1-0.5
Treatment of bacterial enteritis caused by *Escherichia coli* and Salmonella *choleraesuis* susceptible to oxytetracycline and treatment of bacterial pneumonia caused by *Pasteurella multocida* susceptible to oxytetracycline	10 mg/lb of body weight daily Feed continuously for 7-14 days	1[1]
For breeding swine for control and treatment of Leptospirosis (reducing the incidence of abortion and shedding of leptospirae) caused by Leptospira pomona susceptible to oxytetracycline	10 mg/lb of body weight daily Feed continuously for not more than 14 days	1[1]
CALVES INCLUDING PRE-RUMINATING (VEAL) CALVES, BEEF CATTLE, AND NONLACTATING DAIRY CATTLE		
For calves (up to 250 lb) for increased rate of weight gain and Improved feed efficiency	0.05-0.1 mg/lb of body weight daily Feed continuously	0.05-0.1[2]
For calves (250-400lb) for increased rate of weight gain and improved feed efficiency	25 mg/head/day Feed continuously	0.25[4]
For growing cattle (over 400 lb) for Increased rate of weight gain, improved feed efficiency, and reduction of liver condemnation due to liver abscesses	75 mg/head/day Feed continuously	0.75[4]
Prevention and treatment of the rarly stages of shipping fever complex (feed 3-5 days before and after arrival in feedlots)	0.5-2.0 g/head/day	5-21[4]
Treatment of bacterial enteritis caused by *Escherichia coli* and bacterial pneumonia (shipping fever complex) caused by *Pasteurella multocida* susceptible to oxytetracycline	10 mg/lb of body weight daily Feed continuously for 7-14 days	50
▶ WARNING: When used in milk replacers, the treatment claim (10 mg/lb) is limited to bacterial enteritis caused by *Escherichia coli* only. ◀		
SHEEP		
Increased rate of weight gain and improved feed efficiency	10-20 g/ton Feed continuously	0.1-0.2
Treatment of bacterial enteritis caused by *Escherichia coli* and bacterial pneumonia caused by *Pasteurella multocida* susceptible to oxytetracycline	10 mg/lb of body weight daily Feed continuously for 7-14 days	1[4]
▶ WARNING: 5-day withdrawal prior to slaughter at 10 mg/lb dosage. ◀		
LOBSTERS		
Control of gaffkemia in lobsters caused by *Aerococcus viridans*	1 g/lb of medicated feed Feed for 5 days as the role ration	20
▶ WARNING: Withdraw from feed 30 days before harvesting lobsters. ◀		

[1] If bird weighs 10 lb, consuming 0.6 lb of complete feed per day
[2] If pig weighs 100 lb, consuming 4 lb of complete feed per day
[3] If calf weighs 100 lb, consuming 2 lb of complete starter feed per day
[4] Include In feed supplement based on consumption of 2 lb of supplement per head per day
[5] If animal weighs 500 lb, consuming 2 lb of supplement per head per day
[6] If lamb weighs 60 lb, consuming 1 lb of supplement per head per day

101-9002-02 FOR USE IN DRY FEEDS ONLY. NOT FOR USE IN LIQUID FEED SUPPLEMENTS.

TM-100® D

Type A Medicated Article

Phibro
ANIMAL HEALTH

TM-100® D

TYPE A
MEDICATED ARTICLE

Active Drug Ingredient:
Oxytetracycline (from oxytetracycline quaternary salt) equivalent to oxytetracycline hydrochloride .... 100 g/lb

CAUTION: For use in manufacturing medicated animal feeds only.

CAUTION: Certain components of animal feeds, including medicated premixes, possess properties that may be a potential health hazard or a source of personal discomfort to certain individuals who are exposed to them. Human exposure should, therefore, be minimized by observing the general industry standards for occupational health and safety.

Precautions such as the following should be considered: dust masks or respirators and protective clothing should be worn; dust-arresting equipment and adequate ventilation should be utilized; personal hygiene should be observed; wash before eating or leaving a work site; be alert for signs of allergic reactions—seek prompt medical treatment if such reactions are suspected.

STORE IN A DRY, COOL PLACE

SEE BACK PANEL FOR COMPLETE MIXING AND USE DIRECTIONS AND WARNINGS

TM-100 is a Phibro Animal Health registered trademark for Oxytetracycline HCl
Phibro Animal Health, Inc., Fairfield, NJ 07004

Net Weight 50 lb (22.6 kg)

NADA #8-804, Approved by FDA
7921000
101-0004-02

Phibro
ANIMAL HEALTH

TM-100® D

Type A Medicated Article

(01) 1 03 66104 79210 2

TM-100® D

TAKE TIME — OBSERVE LABEL DIRECTIONS

Mixing and Use Directions

Phibro
ANIMAL HEALTH
Fairfield, NJ 07004

TM-100® D

TYPE A MEDICATED ARTICLE

Active Drug **Ingredient:**
Oxytetracycline (from oxytetracycline quaternary salt) equivalent to
oxytetracycline hydrochloride ..... 100 g/lb

CAUTION: For use in manufacturing medicated animal feeds only.

CAUTION: Certain components of animal feeds, including medicated premixes, possess properties that may be a potential health hazard or a source of personal discomfort to certain individuals who are exposed to them. Human exposure should, therefore, be minimized by observing the general industry standards for occupational health and safety.

Precautions such as the following should be considered: dust masks or respirators and protective clothing should be worn; dust-arresting equipment and adequate ventilation should be utilized; personal hygiene should be observed; wash before eating or leaving a work site; be alert for signs of allergic reactions—seek prompt medical treatment if such reactions are suspected.

STORE IN A DRY, COOL PLACE

SEE BACK PANEL FOR COMPLETE MIXING AND USE DIRECTIONS AND WARNINGS

Phibro Animal Health, Inc., Fairfield, NJ 07004

Net Weight 50 lb (22.6 kg)

NADA #8-804, Approved by FDA
7921*000*
101-9004-02

TM-100D

TAKE TIME  OBSERVE LABEL DIRECTIONS

Mixing and Use Directions

Thoroughly mix the amount of this premix according to the directions below with at least an equal amount by weight of iced formula ingredients prior to blending into a complete iced

Indications for Use	Oxytetracycline Amount	lb of TM-100D/ton
CHICKENS		
Increased rate of weight gain and improved feed efficiency	10-50 g/ton Feed continuously	0.1-0.5
Control of infectious synovitis caused by Mycoplasma *synoviae*; control of fowl cholera caused by *Pasteurella multocida* susceptible to oxytetracycline	100-200 g/ton Feed continuously for 7-14 days	1-2
Control of chronic respiratory disease (CRD) and air sac infection caused by *Mycoplasma gallisepticum* and *Escherichia coli* susceptible to oxytetracycline	400 g/ton Feed continuously for 7-14 days	4
Reduction of mortality due to air sacculitis (air sac infection) caused by *Escherichia coli* susceptible to oxytetracycline	500 g/ton Feed continuously for 5 days	5
WARNING: At 500 g/ton level, withdraw 24 hours prior to slaughter. Zero-day withdrawal period for lower use levels. In low calcium feeds withdraw 3 days before slaughter. Do not administer to chickens producing eggs for human consumption.		
TURKEYS		
For growing turkeys for increased rate of weight gain and improved feed efficiency	10-50 g/ton Feed continuously	0.1-0.5
Control of hexamitiasis caused by *Hexamita meleagridis* susceptible to oxytetracycline	100 g/ton Fed continuously for 7-14 days	1
Control of infectious synovitis caused by *Mycoplasma synoviae* susceptible to oxytetracycline	200 g/ton Feed continuously for 7-14 days	2
Control of complicating bacterial organisms associated with bluecomb (transmissible enteritis, coronaviral enteritis) susceptible to oxytetracycline	26 mg/lb of body weight daily Feed continuously for 7-14 days	8.3[1]
WARNING: At 200 g/ton use level or higher, withdraw 5 days before slaughter. Zero-day withdrawal period for lower use levels. Do not administer in turkeys producing eggs for human consumption.		
SWINE		
Increased rate of weight gain and improved feed efficiency	10-50 g/ton Feed continuously	0.1-0.5
Treatment of bacterial enteritis caused by *Escherichia coli* and *Salmonella choleraesuis* susceptible to oxytetracycline and treatment of bacterial pneumonia caused by *Pasteurella multocida* susceptible to oxytetracycline	10 mg/lb of body weight daily Feed continuously for 7-14 days	5[1]
For breeding swine for control and treatment of Leptospirosis (reducing the incidence of abortion and shedding of leptospirae) caused by *Leptospira pomona* susceptible to oxytetracycline	10 mg/lb of body weight daily Feed continuously for not more than 14 days	5[1]
CALVES including pre-ruminating (veal) calves, BEEF CATTLE, AND NONLACTATING DAIRY CATTLE		
For calves (up to 250 lb) for increased rate of weight gain and improved feed efficiency	0.05-0.1 mg/lb of body weight daily Fed continuously	0.05-0.1[3]
For calves (250-400 lb) for increased rate of weight gain and improved feed efficiency	25 mg/head/day Fed continuously	0.25[4]
For growing cattle (over 400 lb) for increased rate of weight gain, improved feed efficiency, and reduction of liver condemnation due to liver abscesses	75 mg/head/day Feed continuously	0.75[4]
Prevention and treatment of the early stages of shipping fever complex (Feed 3-5 days before and after arrival in feedlots)	0.5-2.0 g/head/day	5-20[5]
Treatment of bacterial enteritis caused by *Escherichia coli* and bacterial pneumonia (shipping fever complex) caused by *Pasteurella multocida* susceptible to oxytetracycline	10 mg/lb of body weight daily Feed continuously for 1-14 days	50[6]
WARNING When used in milk replacers, the treatment claim (10 mg/lb) is limited to bacterial enteritis caused by *Escherichia coli* only.		
SHEEP		
Increased rate of weight gain and improved feed efficiency	10-20 g/ton Feed continuously	0.1-0.2
Treatment of bacterial enteritis caused by *Escherichia coli* and bacterial pneumonia caused by *Pasteurella multocida* susceptible to oxytetracycline	10 mg/lb of body weight daily Feed continuously for 7-14 days	12[1]
WARNING: 5-day withdrawal before slaughter at 10 mg/lb dosage.		
HONEY BEES		
Control of American Foulbrood caused by *Bacillus larvae*, and European Foulbrood caused by *Streptococcus pluton* susceptible to oxytetracycline	200 mg/colony	See Mixing Directions below
WARNING: Remove at least 6 weeks prior to main honey flow.		
LOBSTERS		
Control of gaffkemia in lobsters caused by *Aerococcus viridans*	1 g/lb of medicated feed Feed for 5 days as the sole ration	20
WARNING: Withdraw from feed 30 days before harvesting lobsters.		

[1] If bird weighs 10 lb, consuming 0.8 lb of complete feed per day

[2] If pig weighs 100 lb, consuming 4 lb of complete feed per day

[3] If calf weighs 100 lb, consuming 2 lb of complete starter feed per day

[4] Include in feed supplement based on consumption of 2 lb of supplement per head per day

[5] If animal weighs 500 lb, consuming 2 lb of supplement per head per day

[6] If lamb weighs 60 lb, consuming 1 lb of supplement per head per day

FOR USE IN DRY FEEDS ONLY. NOT FOR USE IN LIQUID FEED SUPPLEMENTS.

Mixing and Use Directions for Honey Bees

Due to the high drug concentration of this product, an intermediate mixture must be prepared for use with bees. To prepare this intermediate mixture add 7 lb of TM-100D to 200 lb of powdered sugar and mix well. This mixture contains approximately 200 mg of oxytetracycline hydrochloride activity per oz.

Dusting Directions: Apply 1 oz (200 mg oxytetracycline) of this mixture per colony. Apply the dust on the outer parts or ends of the trimer.

Syrup Directions: Use 1 oz (200 mg oxytetracycline) of this mixture per 5 lb jar containing 1:1 sugar syrup (equal parts sugar and water w/w) per colony. Dissolve in a small quantity of water before adding to syrup. Bulk feed the syrup using feeder pails or division board feeders or by filling the combs.

Administer in 3 applications of sugar syrup or 3 dustings at 4- to 5-day intervals. The drug should be fed in the spring or fall and consumed by the bees before main honey flow begins to avoid contamination of production honey

Extender Patty Directions: Use 4 oz (800 mg oxytetracycline) of this mixture mixed with 165 g of vegetable shortening (Crisco® or equivalent) and 330 g of sugar. The patties are placed on the top bars of the brood nest frames

WARNING: This mixture should be fed in the spring or fall and consumed by the bees before main honey flow begins to avoid contamination of production honey. Honey stored during medication periods in combs for surplus honey should be removed following final medication of the bee colony and must not be used for human food. Honey from bee colonies likely to be infected with foulbrood should not be used for preparation of medicated syrup supplements since it may be contaminated with spores of foulbrood and may result in spreading the disease. Remove at least 6 weeks before main honey flow. Do not use in a manner contrary to state apiary laws and regulations. Each state has specific regulations relative to disease control and medications. Contact the appropriate official or state departments of agriculture for specific inter- and intrastate laws and regulations.

Crisco® is a trademark of Procter & Gamble, Cincinnati, OH 45202

OXYTETRACYCLINE
TYPE B
BAG OR BULK

BLUE BIRD
CATTLE FEED
MEDICATED

ACTIVE DRUG INGREDIENT

Oxytetracycline ..... 20 g/lb

INDICATIONS FOR USE	OXYTETRACYCLINE AMOUNT	lb of Type B/ton of Feed
For calves (up to 250 lb) for increased rate of weight gain and improved feed efficiency	0.05-0.1 mg/lb of body weight daily Feed continuously	0.25-0.5[1]
For calves (250-400 lb) for increased rate of weight gain and improved feed efficiency	25 mg/head/day Feed continuously	1.25[2]
For growing cattle (over 400 lb) for increased rate of weight gain, improved feed efficiency, and reduction of liver condemnation due to liver abscesses	75 mg/head/day Feed continuously	3.75[2]
Prevention and treatment of the early stages of shipping fever complex	0.5-2.0 g/head/day Feed 3-5 days before and after arrival in feed lots	25-100[2]
Treatment of bacterial enteritis caused by *Escherichia coli* and bacterial pneumonia (shipping fever complex) caused by *Pasteurella multocida* susceptible to oxytetracycline	10 mg/lb of body weight daily Feed continuously for 7-14 days	250[3]

GUARANTEED ANALYSIS

Crude Protein (Min) ..... ____%
Equivalent crude protein from Non-Protein Nitrogen (NPN) when added (max) ..... ____%
Crude Fat (Min) ..... ____%
Crude Fiber (Max) ..... ____%
Calcium (Min) ..... ____%
Calcium (Max) ..... ____%
Phosphorus (Min) ..... ____%
Salt (Min) ..... ____%
Salt (Max) ..... ____%
Selenium (Min) ..... ____ppm
Potassium (Min) ..... ____%
Vitamin A (Min) ..... ____IU

INGREDIENTS

Ingredients as defined by AAFCO

WARNING: WHEN USED IN MILK REPLACERS, THE TREATMENT CLAIM (10 MG/LB) IS LIMITED TO BACTERIAL ENTERITIS CAUSED BY *ESCHERICHIA COLI* ONLY.

____lbs (kg) NET WEIGHT

BLUE BIRD FEED MILL
Robin, IN 00000

OXYTETRACYCLINE
TYPE C
BAG OR BULK

BLUE BIRD
CATTLE FEED
MEDICATED

ACTIVE DRUG INGREDIENT

Oxytetracycline..... .5 to 5000 g/ton

INDICATIONS FOR USE	OXYTETRACYCLINE AMOUNT
For calves (up to 250 lb) for increased rate of weight gain and improved feed efficiency	0.05-0.1 mg/lb of body weight daily[1] Feed continuously
For calves (250-400 lb) for increased rate of weight gain and improved feed efficiency	**25** mg/head/day[2] Feed continuously
For growing cattle (over 400 lb) for increased rate of weight gain, improved feed efficiency, and reduction of liver condemnation due to liver abscesses	75 mg/head/day[3] Feed continuously
Prevention and treatment of the early stages of shipping fever complex	0.5-2.0 g/head/day[4] Feed 3-5 days before and after arrival in feed lots
Treatment of bacterial enteritis caused by *Escherichia coli* and bacterial pneumonia (shipping fever complex) caused by ***Pasteurella multocida*** susceptible to osytetracycline	10 mg/lb of body weight daily[5] Feed continuously for 7-**14** days

[1]If a calf weighs 100 lb, consuming **2** lb of complete starter feed **per** day containing 5-10 g/ton oxytetracycline.
[2]Include in feed supplement containing 25 g/ton oxytetracycline based on consumption of **2** lb of supplement per head per day
[3]If a calf weighs 500 lb, consuming 2 lb supplement per head per day containing 75 g/ton oxytetracycline.
[4]Include in a supplement based on consumption of 2 lbs of supplement **per** head **per** day containing 500-2000 g/ton oxytetracycline.
[5]If a calf weighs 500 lbs, consuming 2 lbs of supplement **per** head day containing 5000 g/ton oxytetracycline

GUARANTEED ANALYSIS

Crude Protein (Min) ..... ____%
Equivalent crude protein from Non-Protein Nitrogen (NPN) when added (max). ..... ____%
Crude Fat (Min) ..... ____%
Crude Fiber (Max) ..... ____%
Calcium (Min) ..... ____%
Calcium (Max) ..... ____%
Phosphorus (Min) ..... ____%
Salt (Min) ..... ____%
Salt (Max) ..... ____%
Selenium (Min) ..... ____ppm
Potassium (Min) ..... ____%
Vitamin **A** (Min) ..... ____IU

INGREDIENTS

Ingredients as defined by ***AAFCO***

WARNING: WHEN USED IN MILK REPLACERS, THE TREATMENT CLAIM (10 MG/LB) IS LIMITED TO BACTERIAL ENTERITIS CAUSED BY *ESCHERICHIA COLI* ONLY.

____lbs (____kg) NET WEIGHT

BLUE BIRD FEED MILL
Robin, IN 00000